BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61M 25/00, 25/01

A1

(11) International Publication Number: WO 93/13820

(43) International Publication Date: 22 July 1993 (22.07.93)

(21) International Application Number: PCT/GB93/00030

(22) International Filing Date: 8 January 1993 (08.01.93)

(30) Priority data:
9200496.9 10 January 1992 (10.01.92) GB

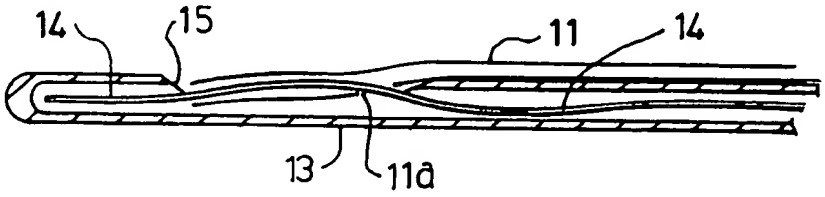
(71)(72) Applicant and Inventor: BROWN, Stephen [GB/GB]; 20 Woodfield Road, Cheadle Hulme, Stockport, Cheshire SK8 7JS (GB).

(74) Agents: McNEIGHT, David, Leslie et al.; McNeight & Lawrence, Regent House, Heaton Lane, Stockport, Cheshire SK4 1BS (GB).

(81) Designated States: AT, AU, BB, BG, BR, CA, CH, DE, DK, ES, FI, GB, HU, JP, KP, KR, LK, LU, MG, MN, MW, NL, NO, PL, RO, RU, SD, SE, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG).

Published
With international search report.

(54) Title: CATHETER INTRODUCTION AND HOLDING SYSTEM



(57) Abstract

There is disclosed a catheter system comprising a flexible tubular probe (11) adapted for introduction to a vessel *via* an out-

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SK	Slovak Republic
CI	Côte d'Ivoire	KZ	Kazakhstan	SN	Senegal
CM	Cameroon	LI	Liechtenstein	SU	Soviet Union
CS	Czechoslovakia	LK	Sri Lanka	TD	Chad
CZ	Czech Republic	LU	Luxembourg	TG	Togo
DE	Germany	MC	Monaco	UA	Ukraine
DK	Denmark	MG	Madagascar	US	United States of America
ES	Spain	ML	Mali	VN	Viet Nam
FI	Finland	MN	Mongolia		

CATHETER INTRODUCTION AND HOLDING SYSTEM.

This invention relates to catheter systems.

For urodynamic measurements it is necessary to insert a probe tube through the urethra into the bladder. Such a probe tube is, however, easily inadvertently expelled.

The present invention provides a catheter system which militates against inadvertent expulsion while enabling the probe to be removed easily when required.

The invention comprises a catheter system comprising a flexible tubular probe adapted for introduction to a vessel via an outlet therefrom, characterised by having an insertion end which, after insertion into the vessel, is formed into a loop whereby to retain the probe against expulsion from the outlet.

The system may comprise rigid fill means adapted to hold the insertion end of the probe in straightened out condition during insertion. The said rigid fill means may comprise a tube with an insertion end opening and a stillette in the tube holding the insertion end of the probe to the opening, the stillette being retractable from the opening, whereby to release the insertion end

of the probe. The stillette may pass into the probe through an aperture in the wall of the probe at the insertion end thereof and extend then further towards the end of the probe to hold said end within the tube for insertion into the vessel.

The insertion end of the probe may be normally formed in a loop which is elastically straightened out for insertion. However, the insertion end of the probe may be normally straight but deformed into a loop after insertion into the vessel. The insertion end of the probe may be deformed by a pull thread extending through the probe up to the insertion end thereof. The pull thread at the insertion end may pass out through the wall of the probe and be attached to the probe nearer the end thereof.

Embodiments of catheter systems according to the invention will now be described with reference to the accompanying drawings, in which :-

Figure 1 is a view of the separate components of a first system;

Figure 2 is a view of the components assembled for insertion;

Figure 3 is an enlarged view of the insertion end of the assembly of Figure 2;

Figure 4 is a view of a probe of a second system;

Figure 5 is a view of the second system assembled for insertion;

Figure 6 is a view of the probe in place after insertion;

Figures 7, 8 and 9 are views illustrating a modified arrangement;

and Figure 10 is a view of a further modified arrangement.

The drawings illustrate catheter systems comprising a flexible tubular probe 11 adapted for introduction to a vessel, such as the bladder of a patient undergoing urodynamical investigation, via an outlet from the vessel (the urethra of such a patient). The probe 11 has an insertion end 12 which, after insertion into the vessel, is formed in a loop, as seen in Figures 1 and 6, Figure 1 being, of course, of the components of the system before assembly for insertion.

The loop 12 is formed, after insertion, in the vessel at the opening in the vessel into the outlet thereof and retains the probe against expulsion from the outlet which otherwise happens unintentionally, for example, when a patient urinates.

In the system illustrated in Figures 1 to 3, the insertion end of the probe 11 falls naturally into the loop configuration shown in Figure 1 and must be straightened out elastically for insertion. This is done using the rigid tube fill means 13 which holds the insertion end of the probe 11 in straightened out condition with the aid of stillette 14.

The tube 13 has an opening 15 at its insertion end and the stillette 14 which extends inside the tube 13 is inserted into the probe 11 through an aperture 11a in the wall thereof, as shown in more detail in Figure 3, and passed through and out of the insertion end of the probe 11 and lodged in the insertion end of the tube 13, which is closed off. This flattens out the natural loop 12 and holds the insertion end of the tube 13 so that the assembly can be introduced into the vessel through the outlet thereof.

Once the insertion end is in the vessel, the stillette 14 is retracted from the insertion end so as

to release the probe 11 which then elastically restores its endwise loop configuration. The fill tube 13 can then be withdrawn from the outlet.

The production of a natural loop at the insertion end of the probe 11 may require the use of relatively expensive plastics materials.

The embodiment of Figures 3 to 6 avoids the production of a natural loop by using a modified probe arrangement. Here, the probe 31 is simply a straight (though of course flexible) piece of plastics tube which is mechanically deformed into a loop at the insertion end 32 after insertion by a pull thread 33 which extends through the probe 31 up to the insertion end 32 thereof, there passing out of the probe 31 through the wall of the probe and being attached to the probe nearer the end thereof, as, in this instance, by passing back into the probe and doubling back through the probe to a pull ring 34 at the distal end.

The insertion procedure is like that used for the embodiment of Figures 1 to 3 with the additional step of pulling on the ring 34 after releasing the insertion end 32 of the probe 31 from the fill tube 13 and before recovering the latter. For convenience, the probe 31 and tube 13 can be clipped together for

insertion, the clip 35 being released prior to recovering of the tube 13.

A connection tube 36 for connecting the probe 31 to test apparatus traps the pull thread 33 to hold the loop against straightening. It is only necessary to release the pull thread 33 by disconnecting the tube 36 to allow the loop to straighten out permitting intentional removal fo the probe 31.

The pull thread 33 should, of course, be able to operate in the probe without jamming, and the dimensions and materials used in manufacture will be selected appropriately.

Figures 7, 8 and 9 illustrate a method of reinforcing the insertion end 12 of the probe 11 against kinking which, in the case of a really fine gauge flexible probe, could kink the probe at its tip into the neck of the bladder (as shown in Figure 8), occluding it. The end 12 is reinforced with an insert 71 around which the pull thread is tied and which is then glued to the lumen of the probe 11.

Figure 7 also illustrates how the pull thread 33 exits the probe 11 near its tip and re-enters it a little further on, which arrangement facilitates loop

formation. Also shown are additional apertures 72 in the probe 11 where it forms the loop 12 - these apertures 72 guarantee that pressure in the probe is in fact bladder pressure, not the pressure at some point within the urethra.

Figure 10 illustrates the pull thread 33 exiting the probe 11 near the distal end thereof the exit aperture 81 being covered by a watertight sleeve 82 - this avoids leakage and loss of measurement pressure due to the presence of the pull thread 33 in an attachment for the connection tube 36.

For a urodynamic catheter system, the probe is desirably some 40 cm in length, the fill tube 13 being for example about 38 cm long for convenience. The fill tube 13 may have an outside diameter of about 3 mm.

CLAIMS

1. A catheter system comprising a flexible tubular probe adapted for introduction to a vessel via an outlet therefrom, characterised by having an insertion end which, after insertion into the vessel, is formed into a loop whereby to retain the probe against expulsion from the outlet.

2. A system according to claim 1, characterised by comprising rigid fill means adapted to hold the insertion end of the probe in straightened out condition during insertion.

3. A system according to claim 2, characterised in that said rigid fill means comprise a tube with an insertion end opening and a stillette in the tube holding the insertion end of the probe to the opening, the stillette being retractable from the opening whereby to release the insertion end of the probe.

4. A system according to claim 3, characterised in that the stillette passes into the probe through an aperture in the wall of the probe at the insertion end thereof and extends then further towards the ends of the probe to hold said end within the tube for insertion into the vessel.

5. A system according to any one of claims 1 to 4, characterised in that the insertion end of the probe is normally formed in a loop which is elastically straightened for insertion.

6. A system according to any one of claims 1 to 4, characterised in that the insertion end of the probe is normally straight but is deformed into a loop after insertion into the vessel.

7. A system according to claim 6, characterised in that the insertion end of the probe is deformed by a pull thread extending through the probe up to the insertion end thereof.

8. A system according to claim 7, characterised in that the pull thread at the insertion end passes out through the wall of the probe and is attached to the probe nearer the end thereof.

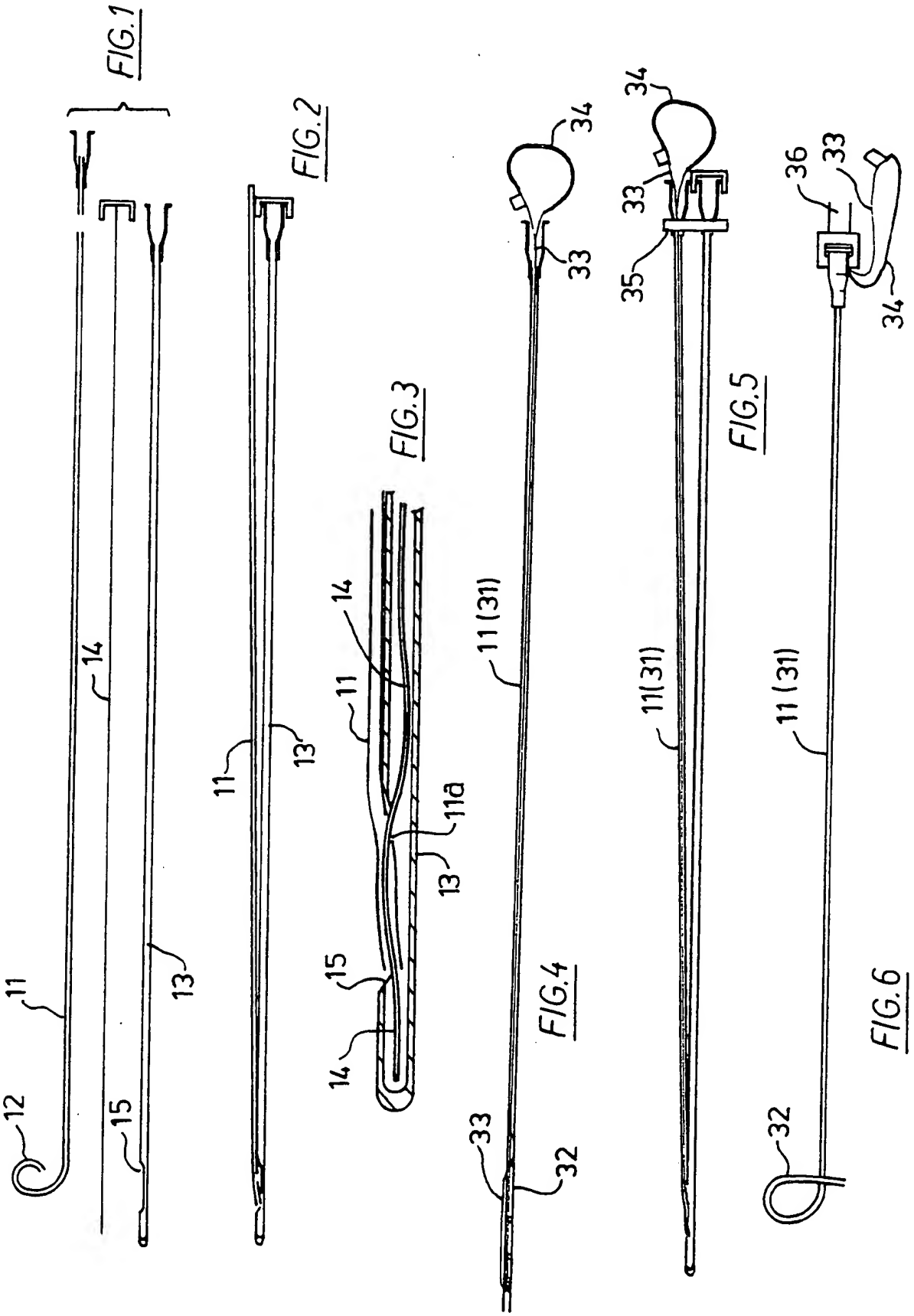


FIG.1
11
12
13
14
15
FIG.2
11
13
FIG.3
11
11a
13
14
15
FIG.4
11(31)
32
33
34
FIG.5
11(31)
33
34
35
FIG.6
11(31)
32
33
34
36

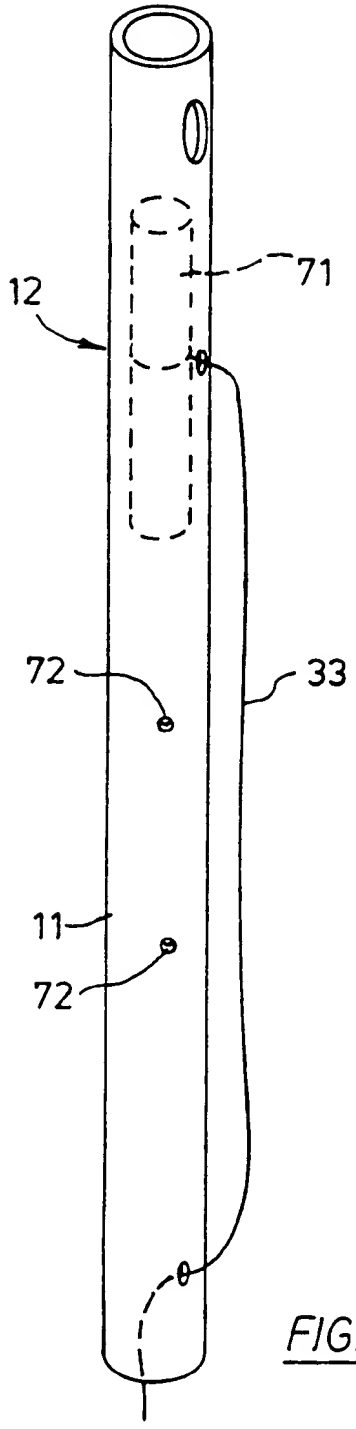


FIG.7

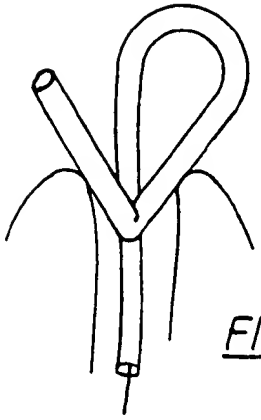


FIG.8

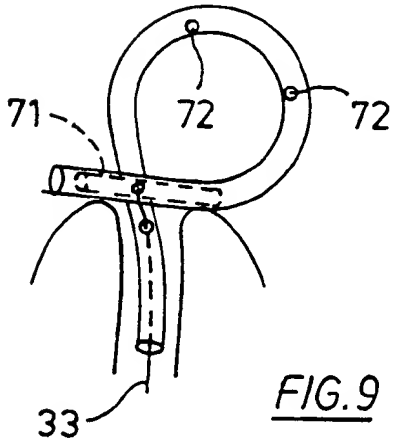


FIG.9

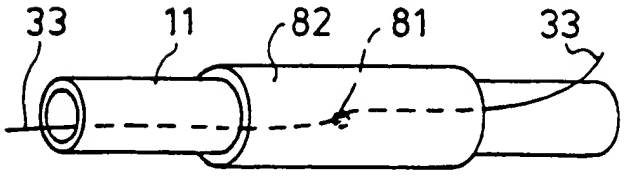


FIG.10

INTERNATIONAL SEARCH REPORT

International Application No PCT/GB 93/00030

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61M25/00; A61M25/01

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61M

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document, [11] with indication, where appropriate, of the relevant passages [12]	Relevant to Claim No.[13]
X	EP,A,0 347 170 (INDIANAPOLIS CENTER FOR ADVANCED RESEARCH INC.) 20 December 1989 see abstract; figures	1-2,5
X	US,A,4 713 049 (CARTER) 15 December 1987 see abstract; figures	1-2,5
X	US,A,4 643 720 (LANCIANO) 17 February 1987 see column 2, line 40 - column 3, line 6; figures	1-2,6-8
A	US,A,3 924 633 (COOK ET AL.) 9 December 1975 see abstract; figures	6-8

° Special categories of cited documents : [10]

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
16 APRIL 1993	29.04.93
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	MIR Y GUILLEN V.

ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO.

GB 9300030
SA 69434

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 16/04/93

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP-A-0347170	20-12-89	US-A- 4986814	22-01-91
		JP-A- 2237573	20-09-90
US-A-4713049	15-12-87	None	
US-A-4643720	17-02-87	EP-A,B 0234364	02-09-87
		JP-C- 1710967	11-11-92
		JP-B- 3077747	11-12-91
		JP-A- 62192174	22-08-87
		US-A- 4740195	26-04-88
US-A-3924633	09-12-75	None	

FORM P0479